



February 15, 1999

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Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204



Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Promotes a Healthy Prostate

Prostate Fatty Acid Complex contains a blend of Omega-3 fatty acids with Saw Palmetto and Pumpkin Seed Oil. Clinical research indicates that regular use of Saw Palmetto provides phytonutrients that may help maintain a healthy prostate.

on the following product:

Tree of Life® Prostate Fatty Acid Complex

Very truly yours,

Leiner Health Products

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Manager of Regulatory Affairs

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